U.S. SMALL BUSINESS ADMINISTRATION
WASHINGTON, D.C. 20416

OFFICE OF CHIEF COUNSEL FOR ADVOCACY

OCT 14 1998

Dr. Michael A. Friedman
Lead Deputy Commissioner
c/o Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Re: Regulatory Flexibility Analysis of the Proposed Rule on Structure or Function Claims/Statements Made for Dietary Supplements; 63 Fed. Reg. 23,624 (April 29, 1998).

Dear Dr. Friedman:

On April 29, 1998, the Food and Drug Administration published a proposed rule outlining definitions of the types of statements that can be made concerning the effect of a dietary supplement on the structure or function of the human body. The proposed rule also establishes criteria for determining when a statement about a dietary supplement is a prohibited disease claim. FDA is attempting to give direction to producers of dietary supplements through this regulation and to respond, in part, to the recommendations and guidance provided by the Commission on Dietary Supplement Labels.

The Office of the Chief Counsel for Advocacy of the U.S. Small Business Administration (SBA) was created in 1976 to represent the views and interests of small businesses in federal policy making activities.[1] The Chief Counsel participates in rulemakings when he deems it necessary to ensure proper representation of small business interests. In addition to these responsibilities the Chief Counsel monitors compliance with the Regulatory Flexibility Act (RFA), and works with federal agencies to ensure that their rulemakings analyze and substantiate the impact that their decisions will have on small businesses.

The Office of Advocacy has been working with FDA on several procedural and technical aspects of this rulemaking. This office had an opportunity to comment informally on this proposal during the OMB review process in March 1998; and FDA consulted with the Office of Advocacy in April 1998 regarding its use of a non-SBA size standard in defining "small business" for the dietary supplement industry. After having had an opportunity to review the proposed rule more thoroughly, these formal comments will address certain inconsistencies in the law arising from the tremendously broad definition of "disease" as proposed and used in this rulemaking. Since the vast majority of the entities affected by this rulemaking are small, expanding the definition of "disease" to include otherwise legal statements about the effects of a product on the normal structure and function of the human body could have a serious and unnecessary economic impact on those small entities.

[1] Regulatory Flexibility Act, 5 U.S.C. § 601, as amended by the Small Business Regulatory Flexibility Act, Pub. L. No. 104-121, 110 Stat. 866 (1996).

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Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), dietary supplements may use claims that a product may affect the structure or function of the body, but may not use claims that they can treat, diagnose, cure or prevent a disease. More specifically, the law allows claims that are truthful and not misleading about the effect of a dietary supplement on the structure or function of the body for maintenance of good health and nutrition without FDA's authorization. Prohibited disease claims, on the other hand, state or imply benefits for a disease, which the proposal defines as "any deviation from, impairment of, or interruption of the normal structure or function of apart, organ, or system (or combination thereof) of the body that is manifested by a characteristics set of signs or symptoms." Dietary supplements that claim to diagnose, treat, etc. a disease continue to be viewed as drugs, and have to meet the safety and effectiveness standards for drugs under the Food Drug and Cosmetic Act (FDCA).

Moreover, to make FDA's new definition of "disease" consistent with the current meaning of "disease or health-related condition" as it exists in 21 C.F.R. § 101.14(a)(6), the regulation proposes the following changes with respect to the terms "disease or health-related condition":

> *(Current definition)* "damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g. hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition . . ."
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> *(Proposed definition)* "any deviation from, impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by a characteristic set of one or more signs or symptoms (including laboratory or clinical measurements that are characteristics of a disease), or a state of health leading to such deviation, impairment, or interruption; except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included within this definition. . ."

Cited throughout FDA's proposed rules are examples of prohibited disease claims: "decreases the effects of alcohol intoxication", "alleviates constipation" (which differs from acceptable claims like, "helps maintain intestinal flora or regularity"), "relieves headache," "improves urine flow in men over 50 years old" (which differs from acceptable claims like, "helps promote urinary tract health"). Intoxication, constipation, tension headache and urine flow of senior citizens would not normally be considered diseases under current law. More importantly, a lay person or consumer probably would not consider the aforementioned conditions to be diseases either—no matter how FDA defines a disease.[2] Intoxication is not alcoholism. Decreased urine flow is not prostate cancer. Tension headache is not a migraine. Constipation is not diverticulitis.

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[2] Under current law, when a structure/function statement (containing health claims) is made, the manufacturer of a dietary supplement must include a prominently displayed disclaimer: "This statement

When ambiguous symptoms become outright diseases, the regulatory water becomes muddied, compliance becomes difficult and the desired goal of reducing confusion becomes lost. Inasmuch as FDA concedes that the instant rulemaking may have a significant economic impact on a substantial number of small entities, the impact on those small entities may be multiplied if it is too difficult to ascertain which structure/function claims are acceptable, or if it is too difficult for consumers to figure out the meaning of a particular claim.

Aside from the practical considerations regarding the goals to be achieved by the proposed rule, there are certain legal inconsistencies that result from expanding the definition of "disease" and treating all structure/function statements in the same manner. For instance, when Congress enacted DSHEA, the following language was added to the definition of "drug":

> "A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement."

This definition presumably was included in section 6 of DSHEA to insure that structure/function claims do not automatically cause products to be deemed drugs (as long as the claims or statements are truthful and not misleading). FDA's proposal would classify as a prohibited claim any claim, that a "[product has] an effect on a consequence of a natural state that presents a characteristic set of signs or symptoms recognizable to health care professionals as constituting an abnormality of the body." FDA's proposal does not seem to mesh with Congress' clear intent to allow certain truthful and non-misleading structure/function claims.

There is more than one type of allowable structure/function claim—a fact not adequately addressed in FDA's proposed rule. Specifically, there are claims that do not trigger drug status for a product and are not health claims. In such cases, notifying FDA about the claims, and the labeling disclaimer that the statement is not FDA approved, are not required. There are also claims which do not trigger drug status and include allowable health claims, but which do trigger FDA notification and a disclaimer. The former class of statements is not subject to 403(r)(6) notice requirements because the claims do not fall within the definition of a "health claim." FDA's definition does not distinguish between structure/function statements that do or do not assert health claims. This failure to distinguish means that more products will be subject to regulation than necessary.

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has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 U.S.C. § 346(r)(6)(C). It is unclear, therefore, how including structure or function claims in the definition of "disease" adds clarity to dietary supplement labeling.

Finally, FDA's cost analysis is not entirely transparent. The cost estimates are not explained (e.g., lower-bound administrative cost estimates are assumed to be $320 per firm for an 18-month compliance period and $425 per firm with a 1-year compliance period). Without knowing what assumptions are used by FDA about the amount of time needed to implement a label revision, there is no way to know whether the administrative cost estimates are valid. Moreover, at least one consultant to the dietary supplement industry has submitted to the Office of Advocacy information indicating that FDA may have underestimated the number of labels affected. One of his distributor clients apparently has 13,276 separate items from 180 separate manufacturing vendors, plus 1650 labels manufactured in house—an average of 74 labels per manufacturer. FDA should ensure that all manufacturing sources of dietary supplements have been identified and considered in order to present an accurate calculation of impact.

The Office of Advocacy believes that FDA should not change the current definition of "disease or health-related condition" in 21 C.F.R. § 101-14(a)(6), and that the agency should not create a new definition of "disease" in 21 C.F.R. § 101.93(g)(1). Instead, FDA might consider listing express examples of claims that comply with current definitions in order to reduce consumer and industry confusion. Moreover, FDA should at least consider clarifying those portions of the regulation that seem to imply that section 403(r)(6) applies when a statement is truthful and not misleading, but is neither a drug claim nor a health claim.

Please do not hesitate to contact our office if you require further clarification of this letter or any other assistance, 202-205-6533.

Sincerely,

Jere W. Glover
Chief Counsel for Advocacy

Shawne Carter McGibbon
Asst. Chief Counsel for Advocacy

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May 14, 1999

Per your telephone call of May 13, 1999, attached is a courtesy copy of the October 14, 1998 letter. The original letter that was sent to you in October of 1998 had part of the last sentence in the 3rd paragraph missing on the first page. This is a corrected copy for your records. Thank you for calling it to our attention.

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